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NOTICE OF ALLOWANCE AND FEE(S) DUE

27730 7590 03/06/2003

DILWORTH PAXSON LLP  
3200 MELLON BANK CENTER  
1735 MARKET STREET  
PHILADELPHIA, PA 19103

EXAMINER

SPIEGEL, MICHAEL A

ART UNIT

CLASS-SUBCLASS

2175

707-100000

DATE MAILED: 03/06/2003

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,289	03/12/2001	John Barthelow Classen	22499-68237	7466

TITLE OF INVENTION: METHOD, SYSTEM AND ARTICLE FOR CREATING AND MANAGING PROPRIETARY PRODUCT DATA

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1300	\$0	\$1300	06/06/2003

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

Applicant claims SMALL ENTITY status.  
See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

## PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Box ISSUE FEE**  
**Commissioner for Patents**  
**Washington, D.C. 20231**  
**Fax (703)746-4000**

**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

**CURRENT CORRESPONDENCE ADDRESS** (Note: Legibly mark-up with any corrections or use Block 1)

27730 7590 03/06/2003

**DILWORTH PAXSON LLP**  
**3200 MELLON BANK CENTER**  
**1735 MARKET STREET**  
**PHILADELPHIA, PA 19103**

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

### Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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nonprovisional	NO	\$1300	\$0	\$1300	06/06/2003

EXAMINER	ART UNIT	CLASS-SUBCLASS
SPIEGEL, MICHAEL A	2175	707-100000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

"Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1. \_\_\_\_\_  
 2. \_\_\_\_\_  
 3. \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent)  individual  corporation or other private group entity  government

4a. The following fee(s) are enclosed:

4b. Payment of Fee(s):

Issue Fee

A check in the amount of the fee(s) is enclosed.

Publication Fee

Payment by credit card. Form PTO-2038 is attached.

Advance Order - # of Copies \_\_\_\_\_

The Commissioner is hereby authorized to charge the required fee(s), or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature) (Date)

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMIT THIS FORM WITH FEE(S)



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DILWORTH PAXSON LLP 3200 MELLON BANK CENTER 1735 MARKET STREET PHILADELPHIA, PA 19103			SPIEGEL, MICHAEL A	
			ART UNIT	PAPER NUMBER
			2175	
DATE MAILED: 03/06/2003				

**Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**  
(application filed on or after May 29, 2000)

The patent term adjustment to date is 298 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 298 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (<http://pair.uspto.gov>)

Any questions regarding the patent term extension or adjustment determination should be directed to the Office of Patent Legal Administration at (703)305-1383.



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27730	7590	03/06/2003	EXAMINER	
			SPIEGEL, MICHAEL A	
		ART UNIT		PAPER NUMBER
		2175		
DATE MAILED: 03/06/2003				

**Notice of Fee Increase on January 1, 2003**

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after January 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on January 1, 2003. See Revision of Patent and Trademark Fees for Fiscal Year 2003; Final Rule, 67 Fed. Reg. 70847, 70849 (November 27, 2002).

The current fee schedule is accessible from: <http://www.uspto.gov/main/howtofees.htm>.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after January 1, 2003 (or mailed with a certificate of mailing on or after January 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

<b>Notice of Allowability</b>	Application #	Applicant(s)
	09/804,289	CLASSEN, JOHN BARTHELOW
	Examiner Michael A Spiegel	Art Unit 2175

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address—

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 03-12-01
2.  The allowed claim(s) is/are 1-137.
3.  The drawings filed on 12 March 2001 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
 of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

5.  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a)  The translation of the foreign language provisional application has been received.
6.  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8.  CORRECTED DRAWINGS must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1)  hereto or 2)  to Paper No. \_\_\_\_\_.
  - (b)  including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1 <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. 5.
5 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. 3.	6 <input type="checkbox"/> Examiner's Amendment/Comment
7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance
	9 <input type="checkbox"/> Other

**DETAILED ACTION**

***Terminal Disclaimer***

1. The terminal disclaimer filed on 2/19/03 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,219,674 has been reviewed and is accepted. The terminal disclaimer has been recorded.

***Allowable Subject Matter***

2. Claims 1-137 allowed.

3. The following is an examiner's statement of reasons for allowance:

Regarding Independent Claim 1, Applicant's particular system for creating and using data associated with a commercially available product, which includes at least one database, comprising together or separately, adverse event data associated with exposure to or use of the product and commercial data regarding marketing, sales, profitability or related information pertaining to the product; a processor for accessing and analyzing data regarding a plurality of different adverse events from the at least one adverse event databases to assist in identifying (i) at least one new adverse event associated with exposure to or use of the product, (ii) at least one new

Art Unit: 2175

use for the product responsive to identification of the at least one new adverse event; and (iii) the potential commercial value of the at least one new use for the product; an adverse event information storage device for storing the new adverse event data of potential commercial value identified with the assistance of the processor; a user node for making requests for adverse event information to, and for receiving adverse event information from the processor; and a user interface for interfacing the processor and the user node, in combination with the other limitations of the claims was not disclosed by, would not have been obvious over, nor would have been fairly suggested by the prior art of record.

The dependant claims, being further limiting to the independent claims, definite and enabled by the specification are also allowed.

Regarding Independent Claim 33, Applicant's particular method for creating and using data associated with a commercially available product, wherein the method comprises the steps of: accessing at least one data source, comprising together or separately, adverse event data associated with exposure to or use of the product and commercial data regarding marketing, sales, profitability or related information

Art Unit: 2175

pertaining to the product; analyzing the accessed data to identify (i) at least one new adverse event associated with exposure to or use of the product, (ii) at least one new use for the product responsive to identification of the at least one new adverse event, and (iii) the potential commercial value of the at least one new use for the product; and commercializing the newly identified product information based upon the analyzed data, in combination with the other limitations of the claims was not disclosed by, would not have been obvious over, nor would have been fairly suggested by the prior art of record.

The defendant claims, being further limiting to the independent claims, definite and enabled by the specification are also allowed.

Regarding Independent Claim 62, Applicant's particular method of establishing at least one commercial new use for a commercially available product, wherein the method comprises the steps of: identifying at least one adverse event associated with exposure to or use of the product; comparing the at least one adverse event with reported or previously known adverse event data associated with exposure to or use of the product; determining that the identified at least one adverse event is a new adverse event associated with exposure to or use

Art Unit: 2175

of the product; analyzing the new adverse event to identify at least one new use for the product responsive to identification of the at least one new adverse event; accessing at least one data source comprising commercial data regarding marketing, sales, profitability or related information pertaining to the product; and determining potential commercial value of the at least one new use for the product based upon the accessed commercial data, in combination with the other limitations of the claims was not disclosed by, would not have been obvious over, nor would have been fairly suggested by the prior art of record.

The dependant claims, being further limiting to the independent claims, definite and enabled by the specification are also allowed.

Regarding Independent Claim 87, Applicant's particular device for processing and managing product-related data, which includes a computer-readable signal-bearing medium; means in the medium for accessing data regarding a plurality of adverse events from at least one database, comprising together or separately, adverse event data associated with exposure to or use of a commercially available product, and wherein at least one database comprises commercial data regarding marketing,

Art Unit: 2175

sales, profitability or related information pertaining to the product means in the medium for processing data regarding a plurality of adverse events from the at least one database to assist in identifying (i) at least one new adverse event associated with exposure to or use of the product, (ii) at least one new use for the product responsive to identification of the at least one new adverse event; and (iii) the potential commercial value of the at least one new use for the product; means in the medium for storing new adverse event data of potential commercial value; and means in the medium for requesting and for receiving new adverse event data, in combination with the other limitations of the claims was not disclosed by, would not have been obvious over, nor would have been fairly suggested by the prior art of record.

The dependant claims, being further limiting to the independent claims, definite and enabled by the specification are also allowed.

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Watanabe et al. (U.S. Patent Publication No. 2002/0138305) teaches a drug information processing device, medical record recording device, a drug information providing system, drug information processing program storage medium, and medical record recording program storage medium.

Akers et al. (U.S. Patent No. 6,112,182) teaches a method and apparatus for integrated management of pharmaceutical and healthcare services.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A Spiegel whose telephone number is 703-305-7605. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dov Popovici can be reached on 703-305-3830. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7239 for regular communications and 703-746-7238 for After Final communications.

Art Unit: 2175

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3900.

*Michael Spiegel*

Michael Spiegel  
Patent Examiner  
Technology Center 2100  
February 26, 2003

*DANIEL D. MIZRAHI*  
DANIEL D. MIZRAHI  
PRIMARY PATENT EXAMINER  
TECHNOLOGY CENTER 2100